PSJ3

Exhibit 210B

FindLaw
Legal News and Commentary
http://news.findlaw.com


View your competition's legal record
Start your competitive intelligence today!
Search by Experience | Published Articles | Search!

U.S. Supreme Court

UNITED STATES v. MOORE, 423 U.S. 122 (1975)

423 U.S. 122

UNITED STATES v. MOORE.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT.
No. 74-759.

Argued October 7, 1975
Decided December 9, 1975.

Respondent, a licensed physician registered under the Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., was convicted of knowing and unlawful distribution and dispensation of methadone (a controlled substance or addictive drug used in the treatment of heroin addicts) in violation of 21 U.S.C. 841 (a) (1), which makes it unlawful for "any person" knowingly or intentionally to distribute or dispense a controlled substance, except as authorized by the CSA. The evidence disclosed that respondent prescribed large quantities of methadone for patients without giving them adequate physical examinations or specific instructions for its use and charged fees according to the quantity of methadone prescribed rather than fees for medical services rendered. The Court of Appeals, however, reversed the conviction on the grounds that respondent was exempted from prosecution under 841 by virtue of his status as a registrant and that a registrant can be prosecuted only under 842 and 843, which prescribe less severe penalties than 841. Held: Registered physicians can be prosecuted under 841 when, as here, their activities fall outside the usual course of professional practice. Pp. 131-145.

(a) Only the lawful acts of registrants under the CSA are exempted from prosecution under 841. That section by its terms reaches "any person" and does not exempt (as it could have) "all registrants" or "all persons registered under the Act." The language of the qualified authorization of 822 (b), which authorizes registrants to possess, distribute, or dispense controlled substances to the extent authorized by their registration and in conformity with other CSA provisions, and which was added merely to ensure that persons engaged in lawful activities could not be prosecuted, cannot be fairly read to support the view that all activities of registered physicians are beyond the reach of 841 simply because of their status. Pp. 131-133.

(b) There is no indication in the operative language of 841-843 that Congress intended to establish two mutually exclusive [423 U.S. 122, 123] penalty systems, with nonregistrants to be punished under 841 and registrants under 842 and 843, the fact that the term "registrants" is used in some subsections of 842 and 843 but not in 841 being of limited significance. Moreover, the legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the defendant's status. Pp. 133-135.

(c) It is immaterial whether respondent also could have been prosecuted for the relatively minor offense of violating 829 with respect to the issuing of prescriptions, since there is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for violating 829 is thereby exempted from prosecution under 841 for the significantly greater offense of acting as a drug "pusher." Pp. 135-138.

(d) The scheme of the CSA, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice." Pp. 138-143.

(e) Congress was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients, but it did not intend to exempt from serious criminal penalties those acts by physicians that go beyond the limits of approved professional practice. Pp. 143-145.

(f) Where the statutory purpose is clear, the canon of strict construction of criminal statutes favoring the accused will be satisfied if the words of the statute are "given their fair meaning in accord with the manifest intent of the lawmakers." United States v. Brown, 333 U.S. 18, 25 -26. P. 145.

164 U.S. App. D.C. 319, 505 F.2d 426, reversed and remanded.

POWELL, J., delivered the opinion for a unanimous Court.

Paul L. Friedman argued the cause for the United States. With him on the briefs were Solicitor General Bork, Assistant Attorney General Thornburgh, Acting Assistant Attorney General Keeney, and Sidney M. Glazer.

Raymond W. Bergan argued the cause for respondent. [423 U.S. 122, 124] With him on the brief were Edward Bennett Williams and Harold Ungar.

MR. JUSTICE POWELL delivered the opinion of the Court.

The issue in this case is whether persons who are registered under the Controlled Substances Act (CSA or Act), 84 Stat. 1242, 21 U.S.C. 801 et seq., can be prosecuted under 841 for dispensing or distributing controlled substances. The United States Court of Appeals for the District of Columbia Circuit reversed the conviction of respondent, a licensed physician registered under the Act, on the ground that he was exempted from prosecution under 841 by virtue of his status as a registrant. We reverse and hold that registered physicians can be prosecuted under 841 when their activities fall outside the usual course of professional practice.

I

Dr. Moore was charged, in a 639-count indictment, with the knowing and unlawful distribution and dispensation of methadone (Dolophine), a Schedule II controlled substance, 1 in violation of 21 U.S.C. 841 (a) (1). That subsection provides:

"Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally -

"(1) to manufacture, distribute, or dispense, or [423 U.S. 122, 125] possess with intent to manufacture, distribute, or dispense, a controlled substance . . . ."

The indictment covered a 5 1/2-month period from late August 1971 to early February 1972. It was reduced before trial to 40 counts, and the jury convicted respondent on 22 counts. He was sentenced to concurrent terms of five to 15 years' imprisonment on 14 counts, and to concurrent terms of 10 to 30 years on the remaining eight counts. The second set of sentences was to be consecutive with the first. Fines totaling $150,000 were also imposed. 2

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315928

Methadone is an addictive drug used in the treatment of heroin addicts. If taken without controls it can, like heroin, create euphoric "highs," but if properly administered it eliminates the addict's craving for heroin without providing a "high." The two principal methods of treating heroin addicts with methadone are "detoxification" and "maintenance." Under a maintenance program, the addict is given a fixed dose once a day for an indefinite period to keep him from using heroin. In detoxification the addict is given a large dose of methadone during the first few days of treatment to keep him free of withdrawal symptoms. Then the dose is gradually reduced until total abstinence is reached.

Maintenance is the more controversial method of treatment. During the period covered by the indictment, registration under 822, in itself, did not entitle a physician to conduct a maintenance program. In addition to a 822 registration, the physician who wished to conduct such a program was required to [423 U.S. 122, 126] obtain authorization from the Food and Drug Administration for investigation of a new drug. Dr. Moore's authorization by the FDA was revoked in the summer of 1971, and he does not claim that he was conducting an authorized maintenance program. Instead, his defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner. He testified that he prescribed large quantities of methadone to achieve a "blockade" condition, in which the addict was so saturated with methadone that heroin would have no effect, and to instill a strong psychological desire for detoxification. The Government's position is that the evidence established that Dr. Moore's conduct was inconsistent with all accepted methods of treating addicts, that in fact he operated as a "pusher."

Respondent concedes in his brief that he did not observe generally accepted medical practices. He conducted a large-scale operation. Between September 1971 and mid-February 1972 three District of Columbia pharmacies filled 11,169 prescriptions written by Dr. Moore. These covered some 800,000 methadone tablets. On 54 days during that period respondent wrote over 100 prescriptions a day. In billing his patients he used a "sliding-fee scale" pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from $15 for a 50-pill prescription to $50 for 150 pills. In five and one-half months Dr. Moore's receipts totaled at least $260,000.

When a patient entered the office he was given only the most perfunctory examination. Typically this included a request to see the patient's needle marks (which in more than one instance were simulated) and an unsupervised urinalysis (the results of which were regularly ignored). A prescription was then written for the amount requested by the patient. On return visits - for [423 U.S. 122, 127] which appointments were never scheduled - no physical examination was performed and the patient again received a prescription for whatever quantity he requested. Accurate records were not kept, and in some cases the quantity prescribed was not recorded. There was no supervision of the administration of the drug. Dr. Moore's instructions consisted entirely of a label on the drugs reading: "Take as directed for detoxification." Some patients used the tablets to get "high"; others sold them or gave them to friends or relatives. Several patients testified that their use of methadone increased dramatically while they were under respondent's care. 3

The Court of Appeals, with one judge dissenting, assumed that respondent acted wrongfully but held that he could not be prosecuted under 841. 4 164 U.S. [423 U.S. 122, 128] App. D.C. 319, 505 F.2d 426 (1974). The court found that Congress intended to subject registered physicians to prosecution only under 842 and 843, 5 which prescribe [423 U.S. 122, 129] less severe penalties than 841. 6 The court reasoned:

> ". . . Congress intended to deal with registrants primarily [423 U.S. 122, 130] through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties provided for in 841 for those seeking to avoid regulation entirely by not registering." 164 U.S. App. D.C., at 323, 505 F.2d, at 430.

It said, further, that 842 and 843 were enacted to enforce that scheme, while 841 was reserved for

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315929

prosecution of those outside the "legitimate distribution chain." Persons registered under the Act were "authorized by [the] subchapter" within the meaning of 841 and thus were thought to be immunized against prosecution under that section. 7 [423 U.S. 122, 131]

Respondent advances two basic arguments, contending that each requires affirmance of the Court of Appeals: (i) as that court held, registered physicians may be prosecuted only under 842 and 843; and (ii) in any event, respondent cannot be prosecuted under 841 because his conduct was "authorized by [the] subchapter" in question. We now consider each of these arguments.

II

A

Section 841 (a) (1) makes distribution and dispensing of drugs unlawful "[e]xcept as authorized by this subchapter . . . ." Relying on this language, the Court of Appeals held that a physician registered under the Act is per se exempted from prosecution under 841 because of his status as a registrant. We take a different view and hold that only the lawful acts of registrants are exempted. By its terms 841 reaches "any person." It does not exempt (as it could have) "all registrants" or "all persons registered under this Act."

The Court of Appeals relied also on 822 (b), which provides: "Persons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." This is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons. This limitation is emphasized by the subsection's heading "Authorized activities," which parallels the headings of 841-843 "Unlawful acts." We think the statutory language cannot fairly be read to support the view that all activities of registered physicians [423 U.S. 122, 132] are exempted from the reach of 841 simply because of their status.

If 822 (b) were construed to authorize all such activities, thereby exempting them from other constraints, it would constitute a sharp departure from prior laws. But there is no indication that Congress had any such intent. Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA. In Jin Fuey Moy v. United States, 254 U.S. 189 (1920), the Court affirmed the conviction of a physician on facts remarkably similar to those before us (e. g., no adequate physical examination, the dispensing of large quantities of drugs without specific directions for use, and fees graduated according to the amount of drugs prescribed). A similar conviction was upheld in United States v. Behrman, 258 U.S. 280 (1922), where the defendant-doctor had prescribed heroin, morphine, and cocaine to a person whom he knew to be an addict.

In enacting the CSA Congress attempted to devise a more flexible penalty structure than that used in the Harrison Act. H. R. Rep. No. 91-1444, Pt. 1, pp. 1, 4 (1970). 8 Penalties were geared to the nature of the violation, including the character of the drug involved. But the Act was intended to "strengthen," rather than to weaken, "existing law enforcement authority in the field of drug abuse." 84 Stat. 1236 (1970) (preamble). See also H. R. Rep. No. 91-1444, p. 1.

Section 822 (b) was added to the original bill at a late date 9 to "make it clear that persons registered under [423 U.S. 122, 133] this title are authorized to deal in or handle controlled substances." H. R. Rep. No. 91-1444, p. 38. It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act, for physicians and other registrants. Rather, 822 (b) was added merely to ensure that persons engaged in lawful activities could not be prosecuted.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315930

B

Respondent nonetheless contends that 841 and 822 (b) must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems: Persons not registered under the Act are to be punished under 841, while those who are registered are to be subject only to the sanctions of 842 and 843. The latter two sections, the argument goes, establish modest penalties which are the sole sanctions in a system of strict administrative regulation of registrants.

The operative language of those sections provides no real support for the proposition that Congress intended to establish two mutually exclusive systems. It is true that the term "registrants" is used in 842 and 843, and not in 841. But this is of limited significance. All three sections provide that "[i]t shall be unlawful for any person . . . [to commit the proscribed acts]." Two of the eight subsections of 842 (a), one of the five subsections of 843 (a), and 842 (b) further qualify "any person" with "who is a registrant." The other subsections of 842 and 843 are not so limited. In context, "registrant" is merely a limiting term, indicating that the only "persons" who are subject to these subsections are "registrants." 10 There is no indication that "persons" [423 U.S. 122, 134] means "nonregistrants" when introducing the other subsections.

There are other indications that 841, and 842 and 843, do not constitute two discrete systems. Section 843 (b), for example, makes it unlawful for any person to use a communication facility in committing a felony under any provision of the subchapter. But violations of both 841 and 843 lead to felony convictions; criminal violations of 842 are misdemeanors. 11 842 (c) (2) (A), 802 (13); 18 U.S.C. 1. And counsel for respondent agreed at oral argument that registrants can be prosecuted under 841 (a) (2), which prohibits the creation, distribution, dispensing, or possession with intent to distribute or dispense of a "counterfeit substance."

The legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant. The penalties now embodied in 841-843 originated in 501-503 of the Controlled Dangerous Substances Act of 1969. The Report of the Senate Judiciary Committee on that bill described 501 (the counterpart of 841) as applying to "traffickers." S. Rep. No. 91-613, p. 8 [423 U.S. 122, 135] (1969). Section 502 provided "[a]dditional penalties . . . for those involved in the legitimate drug trade," and "[f]urther penalties . . . for registrants" were specified in 503. S. Rep. No. 91-613, p. 9. The House Committee Report on the bill that was to become the CSA explains: "The bill provides for control . . . of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H. R. Rep. No. 91-1444, p. 3. Although this language is ambiguous, the most sensible interpretation is that the penalty to be imposed for a violation was intended to turn on whether the "transaction" falls within or without legitimate channels. All persons who engage in legitimate transactions must be registered and are subject to penalties under 842 and 843 for "[m]ore or less technical violations." H. R. Rep. No. 91-1444, p. 10. But "severe criminal penalties" were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but "primarily for the profits to be derived therefrom." Ibid.

C

Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. Id., at 6; S. Rep. No. 91-613, p. 4; 116 Cong. Rec. 996 (1970) (remarks of Sen. Dodd). It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic. See id., at 1663 (remarks of Sen. Hruska); id., at 998 (remarks of Sen. Griffin).

Recognizing this concern the Court of Appeals suggested that Dr. Moore could be prosecuted under 842 [423 U.S. 122, 136] (a) (1) for having violated the provisions of 829 with respect to the issuing of

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315931

prescriptions. 12 Whether Dr. Moore could have been so prosecuted is not before the [423 U.S. 122, 137] Court. 13 We note, however, that the penalties for such a violation could hardly have been deemed by Congress to be an appropriate sanction for drug trafficking by a registered physician. Indeed, the penalty for conviction under 842 would be significantly lighter than, for example, that applicable to a registrant convicted under 843 for using a suspended registration number. 14 Moreover, a physician who wished to traffic in drugs without threat of criminal prosecution could, if violation of 829 were the sole basis for prosecution, simply dispense drugs directly without the formality of issuing a prescription. Direct dispensing is exempt from 829 and thus is not reached by any subsection of 842 or [423 U.S. 122, 138] 843 so long as the technical requirements are complied with.

But we think it immaterial whether Dr. Moore also could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating 829 is thereby exempted from prosecution under 841 for the significantly greater offense of acting as a drug "pusher." 15

III

Respondent argues that even if Congress did not intend to exempt registrants from all prosecutions under 841, he cannot be prosecuted under that section because the specific conduct for which he was prosecuted was "authorized by [the] subchapter" and thus falls within the express exemption of the section.

The trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice. He instructed the jury that it had to find

> "beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute [423 U.S. 122, 139] [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." App. 123.

The Court of Appeals did not address this argument because it concluded that registrants could not be prosecuted under 841 under any circumstances. But it suggested that if a registrant could be reached under 841 he could not be prosecuted merely because his activities fall outside the "usual course of practice." 164 App. D.C., at 322 n. 11, 505 F.2d, at 429 n. 11.

Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy. Section 2 of that Act required all persons who sold or prescribed certain drugs to register and to deliver drugs only to persons with federal order forms. The latter requirement did not apply to "the dispensing or distribution of any of the aforesaid drugs to a patient by a physician . . . registered under this Act in the course of his professional practice only." 38 Stat. 786. As noted above, Congress intended the CSA to strengthen rather than to weaken the prior drug laws. There is no indication that Congress intended to eliminate the existing limitation on the exemption given to doctors. 16 The difficulty [423 U.S. 122, 140] arises because the CSA, unlike the Harrison Act, does not spell out this limitation in unambiguous terms.

Instead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of "registration." Section 822 (b) defines the scope of authorization under the Act in circular terms: "Persons registered . . . under this subchapter . . . are authorized [to dispense controlled substances] . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." But the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice."

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315932

Registration of physicians and other practitioners 17 is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices. 18 823 (f). In the case of a physician [423 U.S. 122, 141] this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice. 19 The federal registration, which follows automatically, extends no further. It authorizes transactions within "the legitimate distribution chain" and makes all others illegal. H. R. Rep. No. 91-1444, p. 3. Implicit in the registration of a physician is the understanding that he is authorized only to act "as a physician."

This is made explicit in 802 (20), which provides that "practitioner" means one who is "registered . . . by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." This section defines the term "practitioner" for purposes of the Act. It also describes the type of registration contemplated by the Act. That registration is limited to the dispensing and use of drugs "in the course of professional practice or research."

Other provisions throughout the Act reflect the intent [423 U.S. 122, 142] of Congress to confine authorized medical practice within accepted limits. Section 812 (b) (2) includes in its definition of Schedule II drugs a requirement that "[t]he drug [have] a currently accepted medical use with severe restrictions." Registration under the CSA to dispense or to conduct research with Schedule I drugs, which are defined as having "no currently accepted medical use in treatment in the United States," 812 (b) (1) (B), does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use. 823 (f). The record and reporting requirements of 827 are made inapplicable with respect to narcotic drugs in Schedules II through V when they are prescribed or administered "by a practitioner in the lawful course of his professional practice." 827 (c) (1) (A). Section 828 (a) prohibits the distribution of Schedule I and II drugs unless pursuant to specified order forms; 828 (e) makes it unlawful for "any person" to obtain drugs with these order forms "for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research." Section 844 (a) prohibits possession of controlled substances unless the drug was obtained "from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized . . . ." See also 885 (a) (2).

The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." 20 As detailed above, he gave inadequate physical examinations or none at all. [423 U.S. 122, 143] He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher" - not as a physician.

IV

Respondent further contended at trial that he was experimenting with a new "blockade" theory of detoxification. The jury did not believe him. Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories. But respondent's interpretation of the Act would go far beyond authorizing legitimate research and experimentation by physicians. It would even compel exemption from the provisions of 841 of all "registrants," including manufacturers, wholesalers, and pharmacists - in addition to physicians.

In enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, Title II of which is the CSA, Congress faced the problem directly. Because of the potential for abuse it decided

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315933

that some limits on free experimentation with drugs were necessary. But it was also aware of the concern expressed by the Prettyman Commission:

> "[A] controversy has existed for fifty years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict.
>
> . . . . .
>
> "The practicing physician has . . . been confused as to when he may prescribe narcotic drugs for an [423 U.S. 122, 144] addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients." 21

Congress' solution to this problem is found in 4 of Title I of the 1970 Act, 42 U.S.C. 257a. That section requires the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction . . . ." It was designed "to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients." H. R. Rep. No. 91-1444, p. 14. Congress pointed out that "criminal prosecutions" in the past had turned on the opinions of federal prosecutors. Under the new Act, "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers . . . ." Id., at 15. The negative implication is that physicians who go beyond approved practice remain subject to serious criminal penalties.

In the case of methadone treatment the limits of approved practice are particularly clear. As Dr. Moore admitted at trial, 22 he was authorized only to dispense methadone for detoxification purposes. His authorization by the FDA to engage in a methadone maintenance program had been revoked. Nor was respondent unfamiliar with the procedures for conducting a legitimate detoxification program. Charges arising [423 U.S. 122, 145] out of his 1969 treatment program, which involved a combination of "long term" and "short term" detoxification, were dropped after he testified before a grand jury and agreed to abide by certain medical procedures in future methadone programs. These included obtaining a medical history of each patient, conducting a reasonably thorough physical examination, abiding by the results of urine tests, recording times and amounts of dosages, and either administering the methadone in his office or prescribing no more than a daily dosage. 23 At trial respondent admitted that he had failed to follow these procedures. 24

V

Respondent argues finally that the statute is sufficiently ambiguous that it must be construed in his favor despite the clear intent of the Congress. It is true that "when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite." United States v. Universal C. I. T. Credit Corp., 344 U.S. 218, 221 -222 (1952). In this case, however, the principle set forth in United States v. Brown, 333 U.S. 18, 25 -26 (1948), is appropriately followed:

> "The canon in favor of strict construction [of criminal statutes] is not an inexorable command to override common sense and evident statutory purpose. . . . Nor does it demand that a statute be given the `narrowest meaning'; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers." [423 U.S. 122, 146]

The judgment of the Court of Appeals is reversed. Because of its disposition of the case, that court did not reach the question whether respondent could be sentenced under 21 U.S.C. 845, which provides a higher penalty for distribution of controlled substances to persons under 21 years of age. We remand for

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315934

the sole purpose of considering respondent's claim that he was improperly sentenced under that section.

So ordered.

Footnotes

[Footnote 1] A substance listed in Schedule II has "a high potential for abuse," "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and is a drug the abuse of which "may lead to severe psychological or physical dependence." 21 U.S.C. 812 (b) (2). Methadone is listed as a Schedule II drug in 812 (c), Schedule II (b) (11).

[Footnote 2] In addition, Dr. Moore's license to practice medicine was revoked pursuant to D.C. Code Ann. 2-131 (1973), which authorizes revocation upon the conviction of "any felony." An appeal from the conviction acts "as a supersedeas to the judgment . . . revoking his license . . . ."

[Footnote 3] One patient testified that he was taking approximately two to three pills per day when he started visiting Dr. Moore. By the end of his visits he was taking 30 to 35 pills a day. App. 43. Another patient increased his intake from five to 10 pills a day to almost 70. Id., at 53-54. A third addict, relying on Dr. Moore for drugs, increased his intake from seven pills a day to over 100. Tr. 310.

[Footnote 4] Section 841 (a) provides, in full: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally - "(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or "(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance." "Dispense" is defined in 802 (10) to mean "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . ." Section 802 (11) defines "distribute" to mean "to deliver (other than by administering or dispensing) a controlled substance." "Administer" refers to "the direct application of a controlled substance to the body of a patient . . . ." 802 (2).

[Footnote 5] Section 842 in relevant part provides: "(a) Unlawful acts. "It shall be unlawful for any person - "(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title; "(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration; "(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title; "(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title; "(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter; "(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter; "(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824 (f) or 881 of this title or to remove or dispose of substances so placed under seal; or "(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection. "(b) Manufacture. "It shall be unlawful for any person who is a registrant to manufacture a controlled substance in Schedule I or II which is - "(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or "(2) in excess of a quota assigned to him pursuant to section 826 of this title." [423 U.S. 122, 129] Section 843 provides: "(a) Unlawful acts. "It shall be unlawful for any person knowingly or intentionally - "(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

required by section 828 of this title; "(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person; "(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge; "(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or "(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance. "(b) Communication facility. "It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term `communication facility' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication."

[Footnote 6] Violations of 841, under which respondent was convicted, carry sentences of up to 15 years, fines as high as $25,000, [423 U.S. 122, 130] or both. 841 (b). Knowing violators of 842 are subject at most to imprisonment for one year, a fine of $25,000, or both. There also may be a civil penalty of $25,000 for violation of 842. 842 (c). The penalties for violation of 843 are imprisonment for not more than four years, a fine of not more than $30,000, or both. 843 (c). All three sections impose higher penalties for violations after the first conviction.

[Footnote 7] The decision below stands alone. At the time it was issued it conflicted with the rulings of four other Circuits. Courts of Appeals for the First, Fifth, and Tenth Circuits had held squarely that physicians may be prosecuted under 841. See United States v. Badia, 490 F.2d 296 (CA1 1973); United States v. Collier, 478 F.2d 268 (CA5 1973); United States v. Leigh, 487 F.2d 206 (CA5 1973); United States v. Bartee, 479 F.2d 484 (CA10 1973); United States v. Jobe, 487 F.2d 268 (CA10 1973). The Ninth Circuit also had affirmed the conviction of a physician under 841 (a) (1). United States v. Larson, 507 F.2d 385 (1974). Since the ruling in this case, two other decisions have considered the issue and expressly rejected the analysis of the Court of Appeals for the District of Columbia Circuit. See United States v. Rosenberg, 515 F.2d 190 (CA9 1975); United States v. Green, 511 F.2d 1062 (CA7 1975). The Sixth Circuit has implicitly agreed. It reversed the conviction of a physician and remanded the case for a new trial because the trial court had failed to instruct the jury that physicians are exempt from prosecution under 841 (a) (1) when they dispense or prescribe controlled substances in good faith to patients in the regular course of [423 U.S. 122, 131] professional practice. United States v. Carroll, 518 F.2d 187 (1975).

[Footnote 8] To this end controlled substances were classified in five categories according to their potential for abuse, their promise for treatment, and their psychological and physical effects. 812.

[Footnote 9] Section 822 (b) was added by the House Committee on Interstate and Foreign Commerce. No comparable section was in the Act when it passed the Senate on January 28, 1970.

[Footnote 10] This represents a commonsense recognition by Congress that only a registrant could, for example, distribute drugs "not authorized by his registration," 842 (a) (2), or manufacture substances "not expressly authorized by his registration" or "in excess of [his] [423 U.S. 122, 134] quota." 842 (b) (1), (2). Nor would there be any reason to apply to nonregistrants the penalties for distributing drugs without complying with the labeling and order-form requirements of the Act, 842 (a) (3), 843 (a) (1), for nonregistrants are barred from making any distributions whatsoever.

[Footnote 11] Another subsection which can be sensibly interpreted only if it reaches nonregistrants is

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315936

842 (a) (1), which is limited to "any person - who is subject to the requirements of part C." Part C of the Act, 821-829, covers the provisions for registration and applies to "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes" to do so. 822 (a). Presumably, 842 (a) (1) is so phrased in order to reach those who should have registered but failed to do so.

[Footnote 12] Section 829 provides, in part: "(a) Schedule II substances. "Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353 (b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled. "(b) Schedule III and IV substances. "Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 353 (b) of this title. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. "(c) Schedule V substances. "No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose." The Attorney General's regulations enacted pursuant to 829 required: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [423 U.S. 122, 137] section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR 306.04 (a) (1973) (redesignated as 21 CFR 1306.04 (a) (1975)). The court below suggested that a violation of the "medical purpose" requirement of 306.04 (a) makes a prescription something other than the "written prescription" required by 829. The dissent, which agreed that Dr. Moore could be prosecuted under 842 (a) (1), did not rely on the regulations. It found inherent in the statutory term "prescription" a requirement that the order be issued for a valid medical purpose.

[Footnote 13] On its face 829 addresses only the form that a prescription must take. A written prescription is required for Schedule II substances. 829 (a). Either a written or an oral prescription is adequate for drugs in Schedules III and IV. 829 (b). The only limitation on the distribution or dispensing of Schedule V drugs is that it be "for a medical purpose." 829 (c). The medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation 306.04 makes it explicit. But 829 by its terms does not limit the authority of a practitioner.

[Footnote 14] In addition, a doctor who dispenses a controlled substance not authorized by his registration to another registrant is also covered by 842 and would thus be punished as severely as a doctor who sold drugs solely for financial profit to nonregistrants. 842 (a) (2).

[Footnote 15] Respondent argues that the proper sanction for trafficking physicians is not criminal prosecution, but deregistration or refusal to reregister. But, under respondent's analysis, at the time he was convicted neither penalty could be imposed as a sanction for the conduct in which he engaged. Registration was mandatory for practitioners with state licenses, 823 (f), and could only be suspended or revoked if the state license was revoked or suspended, if the practitioner had "materially falsified" an application under the Act, or if he had been convicted of a drug-related felony. 824 (a). Conviction for a misdemeanor under 842 would be insufficient to support revocation.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315937

[Footnote 16] The Narcotic Addict Treatment Act of 1974 (NATA), 88 Stat. 124, 21 U.S.C. 802, 823, 824 (1970 ed., Supp. IV), modified the registration and revocation procedures provided in the CSA in order to facilitate "more expeditious" criminal prosecutions by making revocation easier. There was no indication that Congress thought that trafficking doctors could escape felony prosecution altogether under pre-NATA law. Rather, it sought to "cure the present difficulty in such prosecutions because of the intricate and nearly impossible burden of establishing what is beyond `the course of professional practice' for [423 U.S. 122, 140] criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian in nature." S. Rep. No. 93-192, p. 14 (1973). Dr. Moore's conviction was cited to illustrate that successful criminal actions could be brought only "in the most aggravated of circumstances . . . after prolonged effort to make undercover penetrations." Id., at 13.

[Footnote 17] "Practitioner" means "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 802 (20).

[Footnote 18] Under 823, registration of manufacturers and nonpractitioner distributors (such as suppliers) is discretionary with the Attorney General. He first must make a finding that registration is consistent (in the case of manufacturers of Schedule I and II drugs) or not inconsistent (in the case of manufacturers of Schedule III-V [423 U.S. 122, 141] drugs and all distributors) with the public interest. In evaluating the public interest the Attorney General is to consider, for example, "maintenance of effective controls against diversion," compliance with applicable state and local law, prior conviction record in drug-related charges, past experience, and (in the case of manufacturers) promotion of technical advances in manufacturing and the development of new substances. Practitioners and pharmacies are automatically entitled to registration to handle drugs in Schedules II-V "if they are authorized to dispense . . . under the law of the State in which they practice." 823 (f).

[Footnote 19] The House Report described the rationale behind 823 (f) as follows: "Practitioners . . . engaged in the distribution chain would be required to be registered, but registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law . . . ." H. R. Rep. No. 91-1444, p. 23 (1970) (emphasis added).

[Footnote 20] The jury was instructed that Dr. Moore could not be convicted if he merely made "an honest effort" to prescribe for detoxification in compliance with an accepted standard of medical practice. App. 124.

[Footnote 21] Report of the President's Advisory Commission on Narcotic and Drug Abuse 56-57 (1963), quoted in H. R. Rep. No. 91-1444, pp. 14-15.

[Footnote 22] App. 101.

[Footnote 23] Id., at 97-100, 116, 136-138.

[Footnote 24] Id., at 97-100. [423 U.S. 122, 147]

Company | Privacy Policy Disclaimer Copyright © 1994-2004FindLaw

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315938

business on June 13, 2001. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

LIST OF SUBJECTS: Chile, tariffs, and imports.

By order of the Commission.
Issued: April 24, 2001.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–10527 Filed 4–26–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–191N]

Dispensing and Purchasing Controlled Substances over the Internet

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Guidance.

SUMMARY: This notice is intended to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing, purchasing, or importing controlled substances. This guidance document explains when controlled substances can be legally purchased from U.S.-based Internet sites. This notice clarifies that consumers must have valid prescriptions to obtain controlled substances legally and that consumers cannot legally purchase controlled substances from foreign supplier Internet sites and have them shipped to the U.S, unless the consumers are registered with DEA as controlled substances importers and are in compliance with all DEA requirements.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Why is This Notice Necessary?

With the advent of Internet pharmacies, DEA registrants and the public have asked how these Internet pharmacies fit into the requirements that currently exist for the prescribing and dispensing of controlled substances. DEA is issuing this notice to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public about the application of current laws and regulations to the use of the Internet for prescribing, dispensing, purchasing, or importing controlled substances.

This document is in the format of questions and answers. The first section provides the context for this notice. The next two sections address issues that apply to DEA registrants and consumers.

General Questions

What are Controlled Substances?

Most drugs that require a prescription from a doctor are not controlled substances. The Controlled Substances Act and its implementing regulations, however, assign certain substances to one of five "schedules." These substances are placed in a schedule based on their potential for abuse, which may lead to physical or psychological dependency. Schedule I substances have no accepted medical use for treatment in the United States and are not available by prescription. Schedule II through V substances have accepted medical use and varying potentials for abuse and dependency. Practitioners (*e.g.*, doctors, dentists, veterinarians, physician assistants, advance practice nurses) who are licensed by a State and registered with DEA may prescribe these substances. Controlled substances include narcotics (pain relievers), stimulants, depressants, hallucinogens, and anabolic steroids. A complete list of controlled substances can be found in Title 21 of the Code of Federal Regulations (CFR) part 1308. Examples of controlled substances are shown below.

Schedule	Example of controlled substances
Schedule I	Heroin, marijuana, mescaline, methcathinone,
Schedule II	Amphetamine, codeine, fentanyl, Hydromorphone, meperidine, methadone, Methylphenidate (Ritalin), morphine, oxycodone, pentobarbital, phencyclidine (PCP), secobarbital
Schedule III	Anabolic steroids, phendimetrazine, and products that contain small quantities of certain schedule II controlled substances, such as codeine, in combination with noncontrolled ingredients, such as aspirin.
Schedule IV	Alprazolam (Xanax), chlordiazepoxide (Librium), diazepam (Valium), lorazepam (Ativan), phenobarbital, phentermine
Schedule V	Buprenorphine and many cough Preparations that contain a limited amount of codeine

What are the Basic Requirements for Prescribing, Dispensing, and Importing Controlled Substances?

Only practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate. Pharmacies filling prescriptions for controlled substances must also be registered with DEA and licensed to dispense controlled substances by the State(s) in which they operate. A prescription not issued in the usual course of professional practice or not for legitimate and authorized research is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled.

Pharmacists must receive written and manually signed prescriptions for Schedule II substances. They may receive oral or faxed prescriptions for Schedules III–V substances provided they confirm the legitimacy of the prescription and the practitioner. Prescriptions for Schedule II substances may not be refilled. Prescriptions for Schedules III–V controlled substances may be refilled five times, but no prescription may be filled or refilled more than six months after the date on which the prescription was issued. Only those people who are registered with DEA as importers and who are in compliance with DEA requirements may have controlled substances shipped into the customs territory or jurisdiction of the U.S. from a foreign country.

DEA regulations covering prescriptions can be found in Title 21 of the Code of Federal Regulations, part 1306; rules on importation are found in 21 CFR 1312.

Why are Internet Sales an Issue?

The Internet is primarily a communications tool that can be used to facilitate any type of business. On-line pharmacies are currently providing access to a full range of pharmaceuticals, including prescription drugs and controlled substances. Many people view the Internet as changing the way in which business is conducted. For controlled substances, however, the Controlled Substances Act and DEA's regulations continue to determine when and how these substances may be obtained. Internet sales must be in accordance with these requirements.

DEA rules affect how controlled substances may be ordered from an Internet pharmacy and the conditions under which such orders are legal. DEA is currently working on a revision to its regulations that will define the conditions under which prescribers may electronically sign and transmit to any pharmacy (retail, mail order, or Internet) prescriptions for controlled substances. Until these revisions are complete, however, use of the Internet for dispensing controlled substances is governed by existing DEA rules, described above.

DEA is issuing this notice to answer questions that legitimate pharmacies and practitioners have about using the Internet as part of their business. DEA is also aware that some Internet sites are engaged in the illegal sale of controlled substances. Consumers may be illegally purchasing controlled substances from these Internet sites without realizing that they are committing a crime. This notice provides information for consumers to help them understand when they may legally purchase controlled substances.

DEA Registrant Questions About Internet Pharmacies

Must my Internet Pharmacy be Registered with DEA?

The actual physical location of the pharmacy which purchases, stores and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with DEA. The web site itself would not require a separate registration unless it is the same physical location, since the web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances from a local pharmacy; these local pharmacies must be registered with DEA. In this case, the Internet "pharmacy" has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations rests with the actual pharmacy where the controlled substances are dispensed.

Your pharmacy must have a license from the State in which the controlled substances are stored and dispensed and, in most instances, from any state in which you plan to conduct business with customers. You should also be aware that many States require licenses for the web site itself since these sites often provide services like patient counseling.

Does the Label on a Prescription I Fill Indicate the Internet Pharmacy or the Registered Location that Filled the Prescription?

The label must list the registered location that dispensed the controlled substance.

Does Being an Internet Pharmacy Change my Responsibilities Under DEA Regulations?

No, you are still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule II Substances?

You may fill valid prescriptions for Schedule II substances if the patient or prescriber provides you with the signed original prescriptions prior to dispensing. Practically, it is unlikely that most patients will want to wait the time required for such a transaction.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule III–V Substances?

You may receive an original signed prescription or a facsimile of the original signed prescription, or an oral prescription, where allowed, which you verify and immediately reduce to writing. You have the responsibility to ensure the legitimacy of the prescription and the prescriber. At this time, DEA does not permit a prescription received via the Internet to be filled. If you receive prescription information transmitted via the Internet, you must contact the prescriber via telephone and receive an oral prescription for the controlled substance, including the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner (21 CFR 1306.05(a)). You must immediately reduce this oral prescription to writing (21 CFR 1306.21(a)).

Does DEA Intend to Allow Electronic Transmission of Prescriptions in the Future?

DEA is currently engaged in a project to determine the requirements for secure electronic transmission of all controlled substance prescriptions between the practitioner and the pharmacy. When completed, these requirements will automatically certify the authenticity of the prescriber, protect the content of the prescription from alteration, and bind the digital signature on the prescription to the actual prescriber and no one else. These requirements will be subject to rulemaking, and you will have an opportunity to comment on them before they are finalized. You can find more information on this project on the DEA web site at http://www.deadiversion.usdoj.gov/ecomm/index.html.

Can Patients Request a Refill of a Controlled Substance Prescription From my Pharmacy by Sending me an email Instead of Calling me on the Telephone?

Yes, the Internet can be used to facilitate communication between you and your patient when your patient is requesting a permissible refill of an existing Schedule III–V controlled substance prescription.

Some Internet Pharmacies have Doctors who Prescribe Substances Based on an on-line Questionnaire. Is this Legal?

Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 CFR 1306.04(a)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and

• Some logical connection exists tween the medical complaint, the dical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a doctor. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone. However, as discussed later in this document, this circumstance is not intended to limit the ability of practitioners to engage in telemedicine. For purposes of this guidance document, telemedicine refers to the provision of health care using telecommunication networks to transmit and receive information including voice communications, images, and patient records.

Some sites recommend to the patient that they not take a new drug before they have a complete physical performed by a doctor. These sites then k the patient to waive the requirement r a physical and to agree to have a physical before taking the drug they purchase via the Internet. An after-the-fact physical does not take the place of establishing a doctor/patient relationship. The physical exam should take place before the prescription is written. These types of activities by Internet pharmacies can subject the operators of the Internet site and any pharmacies or doctors who participate in the activity to criminal, civil, or administrative actions. For DEA registrants administrative action may include the loss of their DEA registration. Additionally, providing false material information to obtain controlled substances could be considered obtaining a controlled substance by fraud and deceit, which is subject to Federal and State penalties.

I am a Practitioner who is Considering Starting an Internet Practice. Can I use the Internet to Facilitate the Prescribing of Controlled Substances?

You may use the Internet to provide information and to communicate with the patient, but it cannot be the sole basis for authorizing prescriptions. If a ctor/patient relationship exists, you n use the Internet to communicate with patients. Where a doctor/patient relationship exists, you may use the Internet to receive requests for treatment. DEA cautions, however, that such requests for treatment should be logical based on your knowledge of the patient's medical history and the medical complaint. You may also use the Internet to receive requests for refills of prescriptions from patients.

I am a Physician. Does the need for a Physical Exam Mean that I Cannot Engage in Telemedicine and Prescribe Controlled Substances?

No, DEA does not intend to limit the ability of doctors to engage in telemedicine. If the patient cannot travel to your office, but you supervise an exam given by a nurse or other professional, you can then prescribe the needed medications based on the results, to the extent that State law allows. In this case, your decision on the appropriateness of the medication is based on facts (symptoms, blood pressure, etc.) that have been verified by a qualified third party and observed by you electronically.

I have Read in the Controlled Substances Act (CSA) that it is a Violation of the law to use a Communications Facility to Facilitate the Illegal sale of a Controlled Substance. Does this Apply to the use of the Internet to Obtain Pharmaceutical Controlled Substances?

Yes, Title 21, United States Code, section 843(b) defines a communication facility as "any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication." Anyone who uses the Internet to facilitate the illegal sale of a controlled substance would be in violation of 21 U.S.C. 843(b), which is punishable by a term of imprisonment of not more than four years and a fine of not more than $30,000. This provision could apply to owners of Internet sites, prescribers, pharmacists, and patients.

Questions for Consumers

Are Internet Pharmacy Sites Legitimate?

Many Internet pharmacy sites are legitimate. These Internet pharmacy sites may vary in the services they provide, but they may fill a prescription for a controlled substance which was issued to you by an authorized practitioner for a legitimate medical purpose. They should confirm the legitimacy of the prescription for a Schedule III–V controlled substance before filling it by contacting the prescriber. They are not authorized to fill a prescription for a Schedule II controlled substance unless they have first received the original signed prescription.

Some Internet sites for pharmacies advertise local pharmacies and usually list the name, address, and telephone number of the local pharmacy closest to you. Many of these sites provide a great deal of information concerning specific diseases or medical conditions, and drug information. Many Internet sites operated by local pharmacies or mail order pharmacies serve as a communication link so that you can request refills of prescriptions, check the status of your prescription, or ask the pharmacist a question. These are appropriate uses of the Internet by pharmacies.

Some sites simply provide information about specific drugs and medical conditions. After obtaining some general information from you, this type of "Internet Pharmacy" will refer you to a specific local pharmacy or a mail order pharmacy to have the prescription that you obtained from your physician filled. These are appropriate uses of the Internet by pharmacies.

Are There Internet Pharmacy Sites That are Not Legitimate?

Some Internet pharmacy sites do not require that you have a prescription from your doctor. These "Internet Pharmacies" require the customer to complete a medical questionnaire. This type of site advises that the information will be reviewed by a doctor, and the drug will be prescribed and sent to you, if appropriate. The medical questionnaire often has most of the questions set so that if the default answers are not changed, the questions are answered in an appropriate manner to obtain the desired drug. Questionnaire sites often require that the customer waive certain rights. This type of pharmacy usually does not name the doctor who will be reviewing the medical questionnaire or provide any information about the qualifications of the doctor. These sites operate in a manner that is not consistent with state laws regarding standards of medical practice and may be engaging in illegal sales of controlled substances (see discussion above).

Some Internet Pharmacy sites are operating in a foreign country and often do not require any prescription before sending controlled substances to you. These sites often advise that there have been changes to the U.S. law that authorize the customer to import a controlled substance into the United States without benefit of a prescription. These types of sites may be engaging in

illegal sales of controlled substances
e discussion below).

it Legal to Buy Controlled Substances From Foreign Internet Sites and Have Them Shipped to the U.S.?

No, having controlled substances shipped to the U.S. is illegal unless you are registered with DEA as an importer and you are in compliance with 21 U.S.C. 952, 953, and 954 and 21 CFR part 1312. Some foreign Internet sites claim they can legally sell these controlled substances; other sites, knowing that such shipments are illegal, advise consumers of ways to avoid having the packages seized by U.S. Customs. The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. 971 and 21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)). DEA regulations further state:

"No person shall import or cause to be imported any controlled substance * * * unless and until such person is
operly registered under the Act (or
empt from registration) and the
dministrator has issued him a permit to do so pursuant to § 1312.13. * * *" (21 CFR 1312.11(a))

Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960).

The CSA Provides a Personal Use Exemption for Controlled Substances Purchased Abroad. Does the Exemption Apply to Controlled Substances Bought from a Foreign Internet Site?

The Controlled Substances Act and DEA regulations allow you a personal use exemption to bring a limited quantity of controlled substances into the U.S. for your use only when you bring the controlled substances across the U.S. border in your possession (21 U.S.C. 956, 21 CFR 1301.26). It does not apply to controlled substances being shipped into the U.S. Purchasing controlled substances on the Internet and having them shipped to you in the U.S. is not permitted by the personal use exemption. Such purchases and shipments would be considered "imports" of the controlled substance
en if the substance is for your
rsonal use. Unless you are registered as an importer and in compliance with the requirements, such shipments are illegal and subject to seizure.

Does it Make a Difference if I Have a Prescription from a U.S. Doctor for Controlled Substances That I Buy From a Foreign Internet Site?

No, the law remains the same. Unless you are registered with DEA as an importer and are in compliance with DEA's requirements, you may not have controlled substances shipped to you in the U.S. from another country.

What are the Things to Consider in Selecting an Internet Pharmacy?

An "Internet Pharmacy" site should provide a physical address for the pharmacy, in addition to the Internet address, and a telephone number for the pharmacy.

Some indicators that the "Internet Pharmacy" may not be legitimate and should not be used as a source for controlled substances are the following:

- The site is not a participant in any insurance plan and requires that all payments be made with a credit card.
- The site requires that you waive some rights before they send you the drugs.
- The site advises you about the law and why it is permissible for you to obtain pharmaceutical controlled substances from foreign countries via the Internet.
- The site does not ask the name, address, or phone number of your current physician.
- The site advises you to have the drugs sent to post office boxes or other locations to avoid detection by U.S. authorities.

I Have Seen a VIPPS Seal on Some Internet Pharmacy Sites. What Does This Mean?

The National Association of Boards of Pharmacy (NABP) has developed a voluntary program called the Verified Internet Pharmacy Practice Sites (VIPPS). The NABP has begun issuing a "seal of approval" to Internet pharmacies that meet standards regarding State licensing and DEA registration. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their State and each State to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The NABP also provides information on whether a pharmacy is licensed and in good standing (see *http://www.nabp.net*).

Are the Rules Different for "Life Style" Drugs?

Some people have applied the phrase "life style drugs" to certain medications, such as Viagra, weight control medications, and tranquilizers. Many of the so-called life style drugs are not controlled substances. If a "life style" drug is a controlled substance, however, it is still subject to all regulations for controlled substances. You must obtain a prescription from a DEA registered prescriber and have it filled by a DEA registered pharmacy.

I Have a Complaint About an "Internet Pharmacy" Site on the Internet That Appears to be Illegally Selling Drugs. Where Should I Send the Complaint?

If the complaint involves a pharmaceutical controlled substance, contact the DEA, Office of Diversion Control, Drug Operations Section, Washington, DC 20537, telephone (202) 307–7194 or your local DEA office (for a list of contacts, see *http://www.dea.gov/agency/domestic.htm*.)

If the complaint involves any pharmaceutical drug other than a controlled substance, contact the U.S. Food and Drug Administration, HFC–230, 5600 Fishers Lane, Rockville, MD 20857, or file a report on the FDA's web site at *http://www.fda.gov/oc/buyonline/buyonlineform.htm*.

If the complaint involves a pharmacist or a physician, you may contact the State Board of Pharmacy or the State Board of Medicine where the doctor or pharmacist is located.

Additionally, you may wish to view other sites on the Internet that are for registering complaints such as the NABP (*http://www.nabp.net*).

Dated: March 19, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 01–10255 Filed 4–26–01; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study

Consumer Menu

VIPPS Home

Search for a Pharmacy

List of Pharmacies

Criteria

Definitions

Resource Links

Report a Site

Comments

In a **July 13, 2004** news release, the Food and Drug Administration made the following statement:

"The Agency believes that *consumers* should look for participation in this type of certification program [VIPPS®] as one method to help *minimize the risks* of getting bad quality drugs from disreputable sources."

FDA

Verified Internet Pharmacy Practice Sites™ (VIPPS®)
Most Frequently Asked Questions

VIPPS® PROGRAM

What is the VIPPS Program?

The Verified Internet Pharmacy Practice Sites™ (VIPPS®) program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection.

How does NABP verify the sites?

Internet-based pharmacy practice sites wishing to become VIPPS-certified submit a detailed application to NABP, which includes the pharmacy's policies and procedures addressing the VIPPS criteria. Licensure information is verified with applicable state boards of pharmacy. The VIPPS team reviews the application, policies, and applicant's Web site, and performs an on-site inspection of the pharmacy's facilities. Once the policies and procedures as well as the operations of the pharmacy appear to meet the intent of the VIPPS criteria, permission to display the VIPPS Seal is granted and the verified information about the pharmacy is posted on the VIPPS Web site. Clicking on the VIPPS Seal links the user to the VIPPS Web site that then verifies that the Seal is indeed posted on a VIPPS-certified site. If so, the user is then shown pharmacy-specific information, including licensure information.

Does NABP regulate online pharmacies?

NABP does not regulate online pharmacies. Regulation of pharmacy practice, whether online or not, is primarily the jurisdiction of the state boards of pharmacy with some federal oversight. The VIPPS program is a voluntary certification program for which Internet pharmacy practice sites may apply. The value of the program to the patient and the Internet pharmacy is that it provides members of the public with a means to assure themselves that the Internet pharmacy they choose is a bona fide, fully licensed facility exercising competent Internet/interstate pharmacy practices.

When was the VIPPS program developed?

In 1999, NABP became aware of the need for this program when consumers contacted several state pharmacy boards to complain about illegal Internet prescribing and dispensing sites posing as legitimate pharmacies. The Association developed the VIPPS program in response to public and regulatory agency concerns regarding safety of Internet pharmacy practices in order to provide a means for the public to distinguish between legitimate and illegitimate online pharmacy practice sites.

Isn't the number of Internet sites far too large to monitor and control?

No. NABP and the regulatory framework of state boards of pharmacy, federal agencies, and the medical community have been working together for several years now to achieve this goal.

Online Pharmacy Questions

How many online pharmacies are out there?

It is difficult, if not impossible, to answer this question accurately, but it is probably fewer than you would think. Illegitimate pharmacies (usually those that offer online prescribing) open and close on a daily basis. One company posing as a legitimate pharmacy may have many URLs or Web addresses, creating the impression that there is a greater number of Internet pharmacies than actually exists. In addition, pharmacies may only register with select search engines. If these search engines are not utilized when performing a search then all pharmacies may not be counted.

How many prescribing sites are out there?

The number of prescribing sites, using patient questionnaires and fee-based cyberspace consultations, as well as sites that sell prescription medications and controlled substances without requiring a "consult," is difficult to estimate. NABP's research indicates that the number of such rogue operators is less than the number of legitimate online dispensing pharmacies.

What's wrong with using a prescribing site to get Viagra® and Xenical®? I don't have to see a doctor and can obtain the medicine with increased privacy and confidentiality; and it's cheaper.

First, the Food and Drug Administration (FDA) restricts the distribution of certain drugs to a prescription-only basis because in certain medical situations they can be dangerous if not taken with ongoing medical consultation. Most regulatory authorities and professional organizations regard online prescribing to be unprofessional, and in some states it is illegal, unless it is done pursuant to a valid, ongoing patient-prescriber relationship that has included an in-person physical examination. Completing only an online questionnaire does not establish a valid patient-prescriber relationship. Moreover, without a physical examination you could receive inappropriate medication and worsen an underlying, undiagnosed, serious medical condition.

As for increased privacy and confidentiality, evidence appears to indicate that illegitimate prescribing sites frequently sell their customer lists to other illegitimate online pharmacy operators and owners of Internet scam and pornography sites. By buying drugs from an illegitimate site you may be designating yourself as someone who is a good target for rip-off schemes.

Frequently, deceived consumers notify us of non-receipt of medications they ordered, and/or credit card charges that illegitimately operating pharmacies refuse to remove. Many also complain that they are unable to contact the pharmacies: phone lines are disconnected or no one answers.

Can I get really cheap prices from pharmacies outside the US?

First, the FDA generally prohibits the importation of foreign-made versions of prescription medications that are commercially available in the US. The safety and efficacy of these medications cannot be guaranteed. Many countries' drug research and control programs are not as safety oriented as those in the U.S. Though some of the drugs advertised by foreign sites may be manufactured by the same name brand international drug manufacturer as you are used to, they usually are not manufactured in FDA inspected facilities that have met FDA standards. Further, sometimes the medications have been subjected to storage conditions that compromised their potency or safety.

Can I get cheap prices from legitimate online pharmacies?

Yes, and more. One of the great benefits to shopping online to fill your prescriptions is the ease with which you can comparison shop. Many pharmacies offer price

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315944

comparisons between their charge and that of other legitimate pharmacies. This is one way to stretch your health care dollar. Many online pharmacies accept prescription benefit insurance coverage as well. In addition, legitimate online pharmacies often offer valuable health care information in a searchable format. VIPPS-certified pharmacies are required to offer their customers free phone consultation with a pharmacist, and many offer free ask-a-pharmacist e-mail service as well.

What are the main advantages of ordering medications online?

Convenience is a major advantage that online pharmacies provide over some of their pharmacy competitors. Consumers' ability to order and receive medications without leaving their home is a tremendous time-saver. Often, drug information and price information may be accessed via the pharmacy's Web site, or this information may be requested via e-mail so the consumer does not have to wait on the phone for an answer or travel to the pharmacy to ask for this information in person.

In addition, online pharmacies may provide more privacy than traditional brick-and-mortar pharmacies. Consumers who are too embarrassed to purchase certain medications or health care products from the local pharmacy may find greater anonymity by ordering these products from an e-pharmacy where staff may not be able to put a "face to a name."

Laws/Regulations

Who regulates online pharmacies?

The state boards of pharmacy have primary responsibility for regulation of online pharmacies. Regulatory authority is mainly exercised by the state board of pharmacy of the state in which the pharmacy is physically located. In addition, most states protect their citizens by licensing "out-of-state pharmacies" that ship medications to patients in their jurisdictions. The same regulations that apply to traditional brick-and-mortar and mail-order pharmacies typically apply to online pharmacies. Federal agencies, such as the FDA and Drug Enforcement Administration (DEA), are also partners with the state boards of pharmacy in this regulatory process. The FDA, however, mainly regulates foreign-based sites and practitioners.

How do I set-up an online pharmacy?

When pharmacists are thinking about setting up an online pharmacy, we encourage them to do their homework and work in conjunction with the state boards of pharmacy. The VIPPS criteria may serve as a solid guideline when an organization plans to expand into interstate/Internet pharmacy practice and seeks to address issues of quality, verifiable relationships, regulatory compliance, and good pharmacy practices.

How does NABP work with government agencies that regulate online pharmacies?

NABP has strong working relationships with the state boards of pharmacy and the federal agencies. Inspector training programs and the VIPPS "Report a Suspicious Site" programs are examples of ways in which NABP helps regulatory agencies monitor and investigate illegitimate pharmacy Web sites.

How are international online sites regulated?

As mentioned earlier, online sites located outside the United States pose the greatest challenges for state and federal regulators. Cooperation with other nations and their regulatory agencies has been and continues to be the key to regulating online international pharmacy sites. NABP is working with a number of international regulatory agencies to establish VIPPS programs for their online pharmacies.

What organization can I contact regarding regulations and online pharmacies?

Your first contact should be the local state board of pharmacy . You may also subscribe to NABPLAW®, NABP's state pharmacy law and rules database, which allows users to research subjects one state at a time or across all 50 states. Annual subscriptions include two updates to assure users' access to the most accurate information possible.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

For more information contact NABP's Publications Desk, or e-mail NABP at custserv@nabp.net.

What if I believe an online pharmacy has dispensed the wrong medication or labeled the medication incorrectly?

Please report these incidents to your local state board of pharmacy as well as the board of pharmacy in the state where the pharmacy is located. You should also contact the pharmacy that mistakenly dispensed the medication. VIPPS pharmacies are required to document, track, and analyze these types of incidents to determine what went wrong and to prevent recurrences.

What are the signs of a suspiciously operating pharmacy?

First, e-pharmacies are suspect if they dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

Second, online pharmacies should have a toll-free phone number as well as a street address posted on their site. If the pharmacy merely has an e-mail feature, so that the sole means of communication between the consumer and the pharmacy is via e-mail, this is a suspect site.

Third, legitimate sites allow consumers to contact pharmacists if they have questions about their medications. If a site does not advertise the availability of pharmacists for medication consultation, it should be avoided.

Many suspiciously operating e-pharmacies have limited numbers of medications that they sell, particularly "lifestyle" medications that treat such conditions and diseases as impotence, obesity, herpes, pain, and acne. Although pharmacies may not sell every medication available in the US, those online pharmacies solely selling lifestyle medications may not be operating legitimately.

What if I believe that an online pharmacy may be operating suspiciously?

Please report suspiciously operating pharmacies to NABP by using the "Report-a-Site" feature in the VIPPS section of our Web site. You may do so anonymously. We also encourage you to report such sites to your local state board of pharmacy, especially if you or a loved one has been harmed. NABP forwards information regarding suspiciously operating sites to the most appropriate regulatory authorities.

What organization covers the security of patient information for online pharmacies?

Security, confidentiality, and privacy are among the chief concerns of patients and health care professionals regarding online pharmacy services. State and federal laws such as the Health Insurance Portability and Accountability Act (HIPAA) protect patient identifiable information. VIPPS and other voluntary certification programs require participating organizations to adhere to and post their privacy policies. In addition, NABP has published guidelines regarding the confidentiality of patient health care information. Please contact NABP, 847/391-4406, for information about obtaining a copy of these guidelines.

Prescriptions/Prescribers

Can a prescription be faxed to the online pharmacy, or does the pharmacy need the original prescription? Does the online pharmacy verify the prescription with the prescriber?

Generally state laws require faxed prescriptions to be received directly from the

prescriber (not the patient) to be valid. Online sites that do not protect the integrity of the original prescription, or that do not verify the authenticity of suspect prescriptions may be in violation of the law. In addition, VIPPS-certified pharmacies must have policies and procedures in place that address these issues. Before you entrust your health to anyone online, look for the VIPPS Seal, and click to verify.

Disclaimer

Last modified: 12-31-01

Home [] Who We Are [] What's New [] Examinations [] Licensure Transfer [] Foundation/State Newsletters [] Pharmacy Law [] PPAD [] VIPPS[] VAWD

Copyright © 2005 by National Association of Boards of Pharmacy.

The information appearing on this Web site is intended to provide information about the activities, programs, and services of the National Association of Boards of Pharmacy. This information is ADVISORY ONLY and the visitor to this Web site assumes sole responsibility for any decisions made based upon its content. NABP disclaims all warranties regarding such information, whether expressed or implied, including, but not limited to, any warranty as to the quality, accuracy, or suitability of this information for any particular purpose.

point616

Pharmacy Menu

VIPPS Home

Instructions

Application Form

Sample Agreement

Program Fees

Seal Guidelines

Email VIPPS Staff

Online Administration

In a **July 13, 2004** news release, the Food and Drug Administration made the following statement:

"The Agency believes that *consumers* should look for participation in this type of certification program [VIPPS®] as one method to help *minimize the risks* of getting bad quality drugs from disreputable sources."

FDA

VIPPS® Certification Process

The VIPPS certification process begins when the applicant submits a VIPPS application form with application fees to NABP. (See Application form and Instructions)

- Upon receipt of the application form and supporting documentation, NABP staff will:
  - Verify all necessary state pharmacy licenses are in good standing
  - Verify the Pharmacist-in-Charge licenses are in good standing
  - Evaluate the submitted support documents against the Interpretive Guide to the VIPPS Criteria
- Notify the applicant if discrepancies arise or clarification is needed.
- After review of the dcoumentation, staff schedules an on-site inspection of the pharmacy to evaluate the applicant's operations, policies and staff for compliance with the VIPPS criteria.
  Inspections may be required:
  - Upon notice of a complaint against a VIPPS certified pharmacy
  - At the request of a participant in the course of VIPPS certification suspension action.
  - Re-inspections of VIPPS-Certified pharmacies are required once every three years.
- Following review of the application materials, verification of submitted information and licensure, and inspection, a written report will be sent to the pharmacy. If the review is satisfactory the report will include:
  - a VIPPS Letter of Agreement to be signed by an authorized representative or agent of the entity with authority to bind the entity
  - an invoice for the first year participation fee.
- Upon receipt of the executed Letter of Agreement and fee, NABP releases a code to the applicant which allows access to a secure area of the VIPPS Web site where the applicant may retrieve and download their VIPPS hyperlink Seal and carry out other administrative functions. Guidelines for the use of the Seal are included in the Letter of Agreement.
- The VIPPS certification is renewable annually following an update of the registration information and re-verification of licensure status.

The entire process from initial application to award of the Seal should take one to two months depending on scheduling and timeliness and quality of the applicant's response.

VIPPS Certified Pharmacies receive:

- NABP/VIPPS hyperlink Seal to display on their Web site. Focus group studies have demonstrated the Seal's power of reassurance to prospective Internet pharmacy users for a number of reasons.
  - To those trusting their health and life to an unknown entity on the Internet, the NABP Seal represents the comfort afforded by a hundred-year heritage of dedication to protecting the public health

through assisting state boards of pharmacy regulating pharmacy practices.
    - The public can access comprehensive company information regarding each VIPPS pharmacy.
    - Patients appreciate the clear, understandable, and professionally reviewed requirements, which allows them to judge the merit of certification for themselves.
    - The certification requirements address their fears and concerns.
- Expanded Internet presence. NABP is committed to supply a network of connections from its Web site to government agencies. NABP is also working to establish referral links to its Web site from not-for-profit organizations and other pharmacy-related websites. Once in the VIPPS site, visitors may search the database for the Internet pharmacy of their choice.
- A comprehensive overview of their pharmacy operations and policies, with suggestions for improvements and streamlining of services.
- VIPPS Pharmacies also may find benefit from access to NABP resources and expertise in licensure, professional credentialing and regulatory compliance.

Disclaimer

Last Modified: February 18, 2005

TOP

Home [] Who We Are [] What's New [] Examinations [] Licensure Transfer [] Foundation/State Newsletters [] Pharmacy Law [] PPAD [] VIPPS[] VAWD [] Human Resources

Copyright © 2005 by National Association of Boards of Pharmacy.

The information appearing on this Web site is intended to provide information about the activities, programs, and services of the National Association of Boards of Pharmacy. This information is ADVISORY ONLY and the visitor to this Web site assumes sole responsibility for any decisions made based upon its content. NABP disclaims all warranties regarding such information, whether expressed or implied, including, but not limited to, any warranty as to the quality, accuracy, or suitability of this information for any particular purpose.

point616

Consumer Menu

VIPPS Home

Search for a Pharmacy

LIST OF PHARMACIES

Criteria

Definitions

Resource Links

Report a Site

Comments

VIPPS Database Search Results

Your search yielded 14 pharmacy(s):

Detail	Web Business Name	Website Address
	accuratepharmacy.com	www.accuratepharmacy.com
	Anthem Prescription	www.anthemprescription.com
	Caremark.com	www.caremark.com
	Clickpharmacy.com	www.clickpharmacy.com
	DrugSource, Inc.	www.drugsourceinc.com
	drugstore.com	www.drugstore.com
	Familymeds.com	www.Familymeds.com
	HOOK SUPERX, Inc, dba CVS/pharmacy	www.cvs.com
	Medco Health Solutions, Inc.	www.medcohealth.com
	Omnicare, Inc dba Care for Life	www.careforlife.com
	Prescription Solutions	www.rxsolutions.com
	RxWEST Pharmacy	www.rxwest.com
	Tel-Drug, Inc./CIGNA	www.teldrug.com
	Walgreens, Co.	www.walgreens.com

Disclaimer

Copyright © 2005 by National Association of Boards of Pharmacy.

The information appearing on this Web site is intended to provide information about the activities, programs, and services of the National Association of Boards of Pharmacy. This information is ADVISORY ONLY and the visitor to this Web site assumes sole responsibility for any decisions made based upon its content. NABP disclaims all warranties regarding such information, whether expressed or implied, including, but not limited to, any warranty as to the quality, accuracy, or suitability of this information for any particular purpose.

point616

Consumer Menu

VIPPS Home

Search for a Pharmacy

List of Pharmacies

CRITERIA

Definitions

Resource Links

Report a Site

Comments

VIPPS® Criteria

Licensure and Policy Maintenance

Qualifying VIPPS Pharmacies (see definitions) must:

1) Provide NABP with the information necessary to verify that the VIPPS pharmacy is licensed or registered in good standing to operate a pharmacy and/or engage in the practice of pharmacy with all applicable jurisdictions;
2) Provide NABP with the information necessary to verify that all persons affiliated with the site, including those affiliated through contractual or other responsible arrangements, that are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions;
3) Maintain and enforce a comprehensive policy and procedure that documents how the pharmacy's policies and procedures are organized, authorized for implementation, revised, retired and archived; and
4) Comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered, and comply with the more stringent law or regulation as determined by conflicts of law rules. VIPPS pharmacies must maintain and enforce policies and procedures that address conflicts of law issues that may arise between individual states or between state and federal laws and regulations. Said policies and procedures must assure compliance with applicable laws including generic substitution laws and regulations, and must prohibit unauthorized therapeutic substitution from occurring without necessary patient or prescriber authorization and outside of the conditions for participation in state or federal programs such as Medicaid.

Prescriptions

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:

5)Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies. Maintain and enforce policies and procedures that assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without there being a pre-existing patient-prescriber relationship that has included an in-person physical examination.

Patient Information

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:

6) Maintain and enforce policies and procedures ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver, in accordance with applicable state law;
7) Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver;
8) Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and
9) Maintain and enforce policies and procedures to assure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information. [The NABP Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Patient Compliance and Patient Intervention Programs

can serve as a useful resource for addressing the confidentiality and security of patient data.]

Communication

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria must:

10) Maintain and enforce policies and procedures requiring pharmacists to offer interactive, meaningful consultation to the patient or caregiver;
11) Maintain and enforce policies and procedures establishing a mechanism for patients to report, and the VIPPS Pharmacy to take appropriate action regarding, suspected adverse drug reactions and errors;
12) Maintain and enforce policies and procedures that provide a mechanism to contact the patient and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan;
13) Maintain and enforce policies and procedures establishing mechanisms to inform patients or caregivers about drug recalls; and
14) Maintain and enforce policies and procedures establishing mechanisms to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications.

Storage and Shipment

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria, must:

15) Ship controlled substances to patients via a secure means that ensures proper delivery and seeks to prevent diversion; and
16) Assure that medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia (USP), during storage and shipment.

Over-the-Counter Products

Qualifying VIPPS Pharmacies must:

17) Comply with all applicable federal and state laws regarding the sale of Over-the-Counter Products identified as precursors to the manufacture or compounding of illegal drugs.

Quality Improvement Programs

Qualifying VIPPS Pharmacies must:

18) Maintain a Quality Assurance/Quality Improvement Program.

Reporting to NABP

Qualifying VIPPS Pharmacies must:

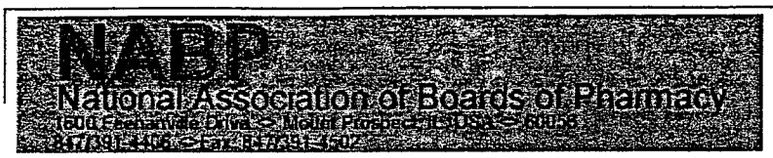
19) Notify NABP within thirty (30) days of any change of information provided as part of the verification process, including change in pharmacist-in-charge, or involving data displayed on the VIPPS Web site. VIPPS pharmacies shall notify NABP in writing within ten (10) days of ceasing operations. The written notification shall include the date the pharmacy will be closed, and an affirmation that all VIPPS Seals and references to the VIPPS program have been removed from the Web site and wherever else they are displayed.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Revised 5/31/05

Disclaimer

TOP



Home
Who We Are
What's New
NABP Newsletter
Examination
Licensure Transfer
Foundation / State Newsletters
Pharmacy Law
PPAD
VIPPS
VIPPS
For Consumers
For Pharmacist
Verified Internet Pharmacies List
VAWD
Human Resources

Who We Are | What's New | Competency Assessment | Licensure | Foundation | Pharmacy Law | PPAD

Consumer Menu

VIPPS Home
Search for a Pharmacy
LIST OF PHARMACIES
Criteria
Definitions
Resource Links
Report a Site
Comments

VIPPS Database Search Results

Your search yielded 14 pharmacy(s):

Detail	Web Business Name	Website Address
	accuratepharmacy.com	www.accuratepharmac
	Anthem Prescription	www.anthemprescriptic
	Caremark.com	www.caremark.com
	Clickpharmacy.com	www.clickpharmacy.co
	DrugSource, Inc.	www.drugsourceinc.co
	drugstore.com	www.drugstore.com
	Familymeds.com	www.Familymeds.com
	HOOK SUPERX, Inc, dba CVS/pharmacy	www.cvs.com
	Medco Health Solutions, Inc.	www.medcohealth.com
	Omnicare, Inc dba Care for Life	www.careforlife.com
	Prescription Solutions	www.rxsolutions.com
	RxWEST Pharmacy	www.rxwest.com
	Tel-Drug, Inc./CIGNA	www.teldrug.com
	Walgreens, Co.	www.walgreens.com

Disclaimer

Home [] Who We Are [] What's New [] Examinations [] Licensure Transfer [] Foundation/State Newslette
Pharmacy Law [] PPAD [] VIPPS[] VAWD [] Human Resources

Copyright © 2005 by National Association of Boards of Pharmacy.

The information appearing on this Web site is intended to provide information about the activities, programs, and services of the I Association of Boards of Pharmacy. This information is ADVISORY ONLY and the visitor to this Web site assumes sole responsi any decisions made based upon its content. NABP disclaims all warranties regarding such information, whether expressed or imp including, but not limited to, any warranty as to the quality, accuracy, or suitability of this information for any particular purpose.

Click here for a printable version of this page

Doctor Finder | Join/Renew | MyAMA | Sits

Home Member Center AMA Agenda Newsroom Professional Resources Med School & Residency About A

Bookstore

AMA Home > PolicyFinder

Policy Finder
Search Tips
About AMA Policy
Download Policy Finder
Principles of Medical Ethics
AMA Strategic Plan and Vision
AMA History

H-120.949 Guidance for Physicians on Internet Prescribing

Our AMA provides the following guidance for physicians on the appropriate use of the Internet in prescribing medications:

(a) Criteria for an acceptable patient (clinical) encounter and follow-up: Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall: (i) obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; (ii)have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); (iii) as appropriate, follow up with the patient to assess the therapeutic outcome; (iv) maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and (v) include the electronic prescription information as part of the patient medical record. Exceptions to the above criteria exist in the following specific instances: treatment provided in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications; and on-call or cross-coverage situations.

(b) Licensure Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside. An exception to this requirement is when the clinical encounter with the patient, as described in recommendation 1(a) above, occurs in the state where the physician is licensed and his or her practice is located, and the state where the patient resides allows electronic prescriptions from out-of-state prescribers.

(c) Security of patient information Physicians who prescribe via the Internet should transmit prescriptions over a secure network (i.e., provisions for password protection, encrypted electronic prescriptions, or other reliable authentication techniques [e.g., AMA Internet ID]) in order to protect patient privacy.

(d) Disclosure of identifying information on web sites Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315955

licensure is held. Posting of actual physicians' license numbers (e.g., the DEA number) is unnecessary.

(e) Liability exposure Physicians should be aware that they may increase their liability exposure by prescribing medications to individuals solely through online interactions (e.g., online questionnaire or online consultation). (BOT Rep. 7, A-03; Reaffirmed: BOT Rep. 3, I-04)

prev / next Results | Back to results list | prev / next Policy number

Search Tips | New Search | Refine Search

© Copyright 1995-2005 American Medical Association. All rights reserved.

Report of the Special Committee on Professional Conduct and Ethics

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State medical Boards of the United States, Inc., April 2002

Introduction

In April 2000, the Federation's House of Delegates adopted 15 recommendations issued by the Special Committee on Professional Conduct and Ethics focusing on physician behaviors and practices which negatively impact (1) patient safety and welfare, and/or (2) the physician-patient relationship. The recommendations pertain to physician activities in five specific areas:

- Disruptive behavior by physicians
- The sale of goods from physician offices
- Boundary issues and patient surrogates
- Participation in business or contractual relationships
- Regulation of Internet prescribing

Recommendation Nine of the Special Committee's Report called for the Federation of State Medical Boards to study the practice of medicine via the Internet as to the impact on public health and safety and develop guidelines for state medical boards to use in educating licensees as to the appropriate use of the Internet in medical practice. Then Federation President George C. Barrett, MD, extended the charge of the Special Committee on Professional Conduct and Ethics to fulfill the adopted recommendation.

In developing the guidelines that follow, the Committee evaluated current and projected use of the Internet in the delivery of health care services and identified two distinct areas of e-health: health information and delivery of patient care. The Committee focused the guidelines on the latter due to its direct impact on patient safety and welfare and the physician-patient relationship.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State medical Boards of the United States, Inc., April 2002

Model Guidelines for the Appropriate use of the Internet in Medical Practice

Section I. Preamble

The Internet has had a profound impact on the practice of medicine and offers opportunities for improving the delivery and accessibility of health care. Studies show a growing number of physicians are utilizing the Internet to some degree in their practices and patients want to receive certain medical services online[1]. However, patient safety concerns, especially as related to providing medical services via the Internet, including prescribing and dispensing medications, have created complex regulatory challenges for state medical boards in protecting the public.

The (*name of board*) recognizes that the Internet offers potential benefits in the provision of medical care. The appropriate application of this technology can enhance medical care by facilitating communication with physicians and other health care

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315957

providers, refilling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. However, it is the expectation of the Board that e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.

The Board has developed these guidelines to educate licensees as to the appropriate use of the Internet in medical practice. The *(name of board)* is committed to assuring patient access to the convenience and benefits afforded by the Internet while promoting the responsible practice of medicine by physicians.

It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain a high degree of professionalism and should:

- Place the welfare of patients first
- Maintain acceptable standards of practice
- Adhere to recognized ethical codes governing the medical profession
- Properly supervise physician extenders
- Protect patient confidentiality

Section II. Parity of Professional and Ethical Standards

There should be parity of ethical and professional standards applied to all aspects of a physician's practice. Related to the use of the Internet in a physician's practice, the Board expects the following ethical standards to be observed:

Candor:
Physicians have an obligation to disclose clearly information (financial, professional, or personal) that could influence patients' understanding or use of the information, products or services offered on any Web site offering health care services or information.

Privacy:
Physicians have an obligation to prevent unauthorized access to or use of patient and personal data and to assure that "de-identified" data cannot be linked back to the user or patient.

Integrity:
Information contained on Web sites should be truthful and not misleading or deceptive. It should be accurate and concise, up to date, and easy for patients to understand. Physicians associated with medical Web sites should strive to ensure that information provided be supported by current medical peer review literature, emanates from a recognized body of knowledge, and conforms to minimal standards of care. It should clearly indicate whether it is based upon scientific studies, expert consensus, professional experience or personal opinion.

Informed Consent:
Delivery of medical services via the Internet requires expanded responsibility on the part of the physician in informing and educating the patient. A patient has the right to know what personal data may be gathered and by whom. The physician must obtain material and informed consent from the patient to collect, share or use personal data. It should be clearly explained to patients when online communication should not take the place of a face-to-face interaction with a health care provider.

Accountability:
Physicians have an obligation to provide meaningful opportunities for patients to give feedback about their concerns and to review and respond to those concerns in a timely and appropriate manner.

Section III. An Appropriate Physician-Patient Relationship

The health and well-being of patients depends upon a collaborative effort between physician and patient.[2] The relationship between physician and patient is complex and is based on the mutual understanding between physician and patient of the shared responsibility for the patient's health care. Although the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician (or ther supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship whether or not interpersonal contact between physician and patient has occurred.

Section IV. Definitions

For the purpose of these guidelines, the following definitions apply:

"**Medical Practice Site**" means a patient-specific Internet site, access to which is limited to licensed physicians, associated medical personnel and patients. It is an interactive site and thus qualifies as a practice location. It requires a defined physician-patient relationship.

"**General Health Information Site**" means a non-interactive Internet site that is accessible by anyone with access to the Internet and intended to provide general, user non-specific information or advice about maintaining health or the treatment of an acute or chronic illness, health condition or disease state.

"**Personal Health Information**" means any personally-identifiable information, whether oral or recorded in any form or medium, that is created or received by a physician or other health care provider and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.[3]

"**Physician-patient e-mail**" means computer-based communication between physicians (or their medical personnel) and patients within a professional relationship in which the physician has taken on an explicit measure of responsibility for the patient's care.[4]

"**Passive tracking mechanism**" means a persistent electronic file used to track Web site navigation, which allows the Web site to record, and retain user-specific navigation information whenever the user accesses the Web site. Examples include "cookies," "clear gifts" or "Web bugs."[5]

"**Web site**" means an electronic source of health information content, commerce, connectivity and/or service delivery.[6]

Section V. Guidelines for the Appropriate Use of the Internet in Medical Practice

The Board has adopted the following guidelines for physicians utilizing the Internet in the delivery of patient care:

Evaluation of the Patient
A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

Treatment
Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

Electronic Communications
Written policies and procedures should be maintained for the use of patient-physician electronic mail. Such policies and procedures should address (1) privacy, (2) health care personnel (in addition to the physician addressee), who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory results must be secure within existing technology (i.e., password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail and medical practice sites should clearly indicate alternative form(s) of communication for urgent matters. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

Informed Consent
A written agreement should be employed documenting patient informed consent for the use of patient-physician e-mail. The agreement should be discussed with and signed by the patient and included in the medical record. The agreement should include the following terms:

- Types of transmissions that will be permitted (prescription refills, appointment scheduling, patient education, etc.)
- Under what circumstances alternate forms of communication or office visits should be utilized
- Security measures, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy
- Hold harmless clause for information lost due to technical failures
- Requirement for express patient consent to forward patient-identifiable information to a third party
- Patient's failure to comply with the agreement may result in physician terminating the e-mail relationship

Medical Records
The medical record should include copies of all patient-related electronic communications, including patient-physician e-mail, prescriptions, laboratory and test results, evaluations and consultations, records of past care and instructions. Informed consent agreements related to the use of e-mail should also be filed in the medical record.

Patient medical records should remain current and accessible for review and be maintained in compliance with applicable state and federal requirements.

Compliance with State and Federal Laws and Web Standards
Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy. Physicians are referred to "Standards for Privacy of Individually Identifiable Health Information" issued by the Department of Health and Human Services (HHS).[7] Guidance documents are available on the HHS Office for Civil Rights Web site at www.hhs.gov/ocr/hipaa.

Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.[8]

Physicians are encouraged to comply with nationally recognized health Web site standards and codes of ethics, such as those promulgated by the American Medical Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC).

Disclosure
Physician medical practice sites should clearly disclose:

- Owner of the site
- Specific services provided
- Office address and contact information

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- Licensure and qualifications of physician(s) and associated health care providers
- Fees for online consultation and services and how payment is to be made
- Financial interests in any information, products or services
- Appropriate uses and limitations of the site, including providing health advice and emergency health situations
- Uses and response times for e-mails, electronic messages and other communications transmitted via the site
- To whom patient health information may be disclosed and for what purpose
- Rights of patients with respect to patient health information
- Information collected and any passive tracking mechanisms utilized

Accountability
Medical practice sites should provide patients a clear mechanism to:

- access, supplement and amend patient-provided personal health information
- provide feedback regarding the site and the quality of information and services
- register complaints, including information regarding filing a complaint with the applicable state medical board(s)

Advertising/Promotion of Goods or Products
Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits or incentives is prohibited.

Links
Physician Web sites may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites.

References

American Accreditation HealthCare Commission. *Health Web Site Standards*. July 2001.

AMA. Council on Ethical and Judicial Affairs. *Code of Medical Ethics*. 2000-2001.

AMA. *Report of the Council on Medical Service. Medical Care Online*. 4-A-01 (June 2001).

College of Physicians and Surgeons of Alberta. Policy Statement. *Physician/Patient Relationships* (February 2000).

Colorado Board of Medical Examiners. *Policy Statement Concerning the Physician-Patient Relationship*.

Federal Register. December 28, 2000.

FSMB. *A Model Act to Regulate the Practice of Medicine Across State Lines*. April 1996.

Health Ethics Initiative 2000. *eHealth Code of Ethics*. May 2000.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315961

Health on the Net Foundation. *Code of Medical Conduct for Medical and Health Web Sites*. January 2000.

Louisiana State Board of Medical Examiners. *Statement of Position. Internet/Telephonic Prescribing*. May 24, 2000.

New York Board for Professional Medical Conduct. *Statements on Telemedicine* (draft document). October 2000.

North Carolina Medical Board. *Position Statement. Documentation of the Physician-Patient Relationship*. May 1, 1996.

Oklahoma Board of Medical Licensure. *Policy on Internet Prescribing*. November 2, 2000.

South Carolina Board of Medical Examiners. *Policy Statement. Internet Prescribing*. July 17, 2000.

Texas State Board of Medical Examiners. *Internet Prescribing Policy*. December 11, 1999.

Washington Board of Osteopathic Medicine and Surgery. *Policy Statement. Prescribing Medication without Physician/Patient Relationship*. June 2, 2000.

Special Committee on Professional Conduct and Ethics

George A. Porter, MD, Chair
Former Chair
Oregon Board of Medical Examiners

Ronnie R. Cox, PhD
Member
Arizona Board of Medical Examiners

John W. Foust, MD
Member
North Carolina Medical Board

Lawrence W. O'Connell, PhD
President
New Hampshire Board of Medicine

Joel C. Pittard, MD
Former Member
Alabama State Board of Medical Examiners

Janet Tornelli-Mitchell, MD
Member
Texas State Board of Medical Examiners

Cheryl E. Winchell, MD
Member
FSMB Board of Directors
Former Member
Maryland Board of Physician Quality Assurance

Terry L. Wolff, DO
Member and Former President
North Dakota State Board of Medical Examiners

Ann Marie Berger, MPA
Executive Director
Arizona Board of Osteopathic Examiners

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABDCMDL00315962

Kathleen Haley, JD
Executive Director
Oregon Board of Medical Examiners

Bruce W. McIntyre, JD
General Counsel
Rhode Island Board of Medical Licensure and Discipline

FSMB Staff:

Bruce A. Levy, MD, JD
Deputy Executive Vice President, Leadership Services
Federation of State Medical Boards

Lisa Robin
Assistant Vice President, Leadership and Legislative Services
Federation of State Medical Boards

---

[1] AMA. Report of the Council on Medical Service, Medical Care Online.

[2] AMA, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship.

[3] Health Web Site Standards, Version 1.0, 2001 URAC

[4] Policy H-478.997, American Medical Association

[5] Health Web Site Standards, Version 1.0, 2001 URAC

[6] Health Web Site Standards, Verson 1.0, 2001 URAC

[7] Federal Register, December 28, 2000.

[8] FSMB. A Model Act to Regulate the Practice of Medicine Across State Lines, (HOD 1996).

Click here to submit comments about this FSMB policy.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

f Federal Regulations]
[Title 21, Volume 9]
[Revised as of April 1, 2005]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR1301.74]

[Page 39-40]

TITLE 21-FOOD AND DRUGS

CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1301_REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES--Table of Contents

Sec. 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Sec. 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ``customer'' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When

[[Page 40]]

storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in Sec. 1301.72. In addition, he registrant shall employ precautions (e.g., assuring that shipping ontainers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

[36 FR 7778, Apr. 24, 1971; 36 FR 13386, July 21, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

Editorial Note: For Federal Register citations affecting Sec. 1301.**74**, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

<DOC>
[

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

INTERNET PHARMACY
Decision Questions

1. Have you physically inspected the pharmacy? _____

2. Does the pharmacy accept walk-in customers? _____

3. Is the pharmacy licensed for sales in all required states? _____

4. Does the pharmacy purchase a wide range of drug products from distributors? _____

5. What percentage of the pharmacy's drug purchases are controlled substances? _____

6. Has the pharmacy requested to pick up orders rather than have them delivered to the pharmacy? _____

7. Is the pharmacy ordering more than 3,000 dosage units of phentermine a month? _____

8. Is the pharmacy ordering more than 5,000 dosage units of hydrocodone combination products a month? _____

9. Is the pharmacy ordering more than 5,000 dosage units of alprazolam a month? _____

what is the web site address

10. If the pharmacy has a web site or is related to a web site:

    a. Are reasonable retail prices listed on the web site? _____
    high prices are bad

    b. Is there a patient medical history questionnaire on the web site? _____
    if so, bad sign

    c. Does the prescribing doctor perform a physical exam of each patient? _____
    must be done to be legal

    d. Does the website accept third party payment (i.e. insurance) for the Internet prescriptions? _____
    if so, good

    e. Does the web site offer to sell drugs without a prescription? _____
    if so, bad

11. Is the pharmacy VIPPS certified? _____

12. Who pays the distributor for the drugs, the pharmacy or a third party? _____

7-29-05